

**QUALITY MANAGEMENT (QM) ACTIVITIES WHICH CAN  
GENERATE CONFIDENTIAL DOCUMENTS**

**1 PURPOSE:** This change to Veterans Health Administration (VHA) Directive 98-016 adds the Sentinel Event Registry, also known as the Patient Safety Registry, to the list of documents generated that are confidential under Title 38 United States Code (U.S.C.) Section 5705 and its revised implementing regulations, dated October 24, 1994.

**2. POLICY:** Only VHA documents that meet the requirements in 38 U.S.C. 5705 and its revised confidentiality regulations are considered confidential.

**3. ACTION:** The following paragraph is added as paragraph 4.b.(2)(e):

(e) Patient Safety Registry

1. The Patient Safety Registry is a central database that is used to report and monitor individual adverse events involving patients treated by Department of Veterans Affairs (VA) in VA facilities. Facility, Veterans Integrated Service Network (VISN) and national VHA components investigate, examine and analyze an event reported to the Patient Safety Registry in order to:

- a. Identify basic or contributing causal factors that resulted in the adverse event; and
- b. Develop protocols or procedures for VHA to adopt that will prevent a recurrence of the event.

2. The Patient Safety Registry usually involves:

- a. The gathering and examination of patient-specific data.
- b. Analysis and coordination of reported events at and between the facility, VISN, and national levels.

3. Analysis of Patient Safety Registry data may involve review of similar events from different facilities in order to derive common causal factors and solutions.

**4. FOLLOW-UP RESPONSIBILITIES:** The National Center for Patient Safety (10X) is responsible for the contents of this Directive.

**5. RESCISSION:** VHA Directive 98-016, change 1, and change 2 expire March 12, 2003.

S/ Melinda Murphy for  
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Acting Under Secretary for Health

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**THIS VHA DIRECTIVE EXPIRES MARCH 12, 2003**